

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALTANA PHARMA AG and WYETH,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,
et al.,

Defendants.

Civil Action No.: 04-2355 (JLL)

OPINION AND ORDER

LINARES, District Judge,

This matter comes before the Court on Plaintiffs’ motion to strike the Teva and Sun Defendants’ new patent misuse defense. Under Federal Rule of Civil Procedure 12(f), “the court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent or scandalous matter.” Fed. R. Civ. P. 12(f). A motion to strike an affirmative defense pursuant to Rule 12(f) is governed by the same standard as a motion to dismiss pursuant to Rule 12(b)(6). A motion to strike an affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances.

On a motion to dismiss pursuant to Rule 12(b)(6), “courts are required to accept all well-pleaded allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party.” Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008). But, “[f]actual allegations must be enough to raise a right to relief above the speculative level.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). Courts are not required to credit bald assertions or legal conclusions draped in the guise of factual allegations. See In re Burlington

Coat Factory Sec. Litig., 114 F.3d 1410, 1429 (3d Cir. 1997). A pleading that offers “labels and conclusions” or a “formulaic recitation of the elements of a cause of action will not do.”

Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Twombly, 550 U.S. at 555). Thus, “stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest’ the required element[s].” Wilkerson v. New Media Tech. Charter Sch. Inc., 522 F.3d 315, 322 (3d. Cir. 2008) (quoting Twombly, 550 U.S. at 556).

However, as this Court has previously stated on the record, striking an affirmative defense “is a drastic remedy, and it is resorted to only when required for the purposes of justice.” In re Gabapentin Patent Litig., 648 F. Supp. 2d 641, 648 (D.N.J. 2002). Motions to strike “are generally viewed with disfavor and will generally be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties or if the allegations confuse the issue.” Garlenger v. Verbeke, 223 F. Supp. 2d 596, 609 (D.N.J. 2002). Such motions are not appropriate when the sufficiency of the defense depends on disputed issues of fact. Further, a motion to strike is not appropriate as a procedure to determine areas of disputed or unclear questions of law. With this framework in mind, the Court now turns to Plaintiff’s motion.

Patent Misuse is defined as the “patentee’s act of ‘impermissibly broadening the physical or temporal scope’ of the patent grant with an anticompetitive effect.” Princo Corp. v. Int’l Trade Comm’n, 616 F.3d 1328 (Fed. Cir. 2010) (citing Windsurfing Int’l, Inc. v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986). When the patentee has used restrictive conditions on licenses or sales to broaden the scope of the patent grant, “[the Federal Circuit has] held that an accused infringer may invoke the doctrine of patent misuse to defeat the patentee’s claim.” See Monsanto

Co. v. McFarling, 363 F.3d 1336, 1341 (Fed.Cir.2004); Va. Panel Corp. v. MAC Panel Co., 133 F.3d 860, 870 (Fed.Cir.1997); Senza-Gel Corp. v. Seiffhart, 803 F.2d 661 (Fed. Cir.1986).

Supreme Court precedent “establishe[s] the basic rule of patent misuse: that the patentee may exploit his patent but may not use it to acquire a monopoly not embraced in the patent.” Princo at 13. “[T]he key inquiry under the patent misuse doctrine is whether, by imposing the condition in question, the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects.” Princo at 8. Therefore, to succeed on a claim for patent misuse a defendant must prove “‘patent leverage,’ i.e. the use of the patent power to impose overbroad conditions on the use of the patent in suit that are not within the reach of the [patent] monopoly” and which have an anticompetitive effect. Princo, 616 F.3d at 1331. (internal quotation marks omitted).

The Teva and Sun Defendants (“Defendants”) allege that Altana (now Nycomed) and Wyeth (“Plaintiffs”) have engaged in patent misuse by amending their existing patent license agreement to treat the ‘579 patent as if it were in force for an additional six months past the expiration date. Specifically, Defendants claim that Wyeth paid Nycomed patent royalties on the ‘579 patent for six months after Nycomed’s statutory patent monopoly expired, until January 19, 2011. Defendants allege that this constitutes an improper extension of the temporal scope of the ‘579 patent and is patent misuse *per se* under Brulotte v. Thys, 379 U.S. 29 (1964).

In Brulotte, Petitioners refused to make royalty payments on a license granted by Respondent that accrued both before and after the expiration of Respondent’s various hop-picking patents. The Supreme Court held that Respondent could not collect after the last of the

patents incorporated into the hop-picking machines had expired. Specifically, the Court wrote “the exaction of royalties for use of a [patented invention] after the patent has expired is an assertion of monopoly power in the post-expiration period when . . . the patent has entered the public domain.” Id. at 33.

Plaintiffs make two arguments as to why their conduct does not constitute patent misuse: 1) they assert that the pediatric exclusivity period extends the patent terms, so that royalties have not really been levied after the expiration date of the ‘579 patents; and 2) they claim that Defendants have failed to adequately plead that the ‘579 patent was leveraged.

A pediatric exclusivity period is granted by the FDA to NDA holders under 21 U.S.C. § 355a. In contrast, a patent term extension is granted by the PTO to patent owners. A pediatric exclusivity period is granted because the NDA holder performs and reports on tests that the FDA requests it to do. It provides that, for six months after the patent on the drug expires, it will not permit anyone else, subject to certain exceptions, to market the finished drug product described in the NDA. The FDA has stated, “[p]ediatric exclusivity . . . is not a patent term extension under 35 U.S.C. § 156. Rather, it extends the period during which approval of an abbreviated new drug application (ANDA) . . . may not be made effective by the FDA.” Guidance for Industry: Qualifying for Pediatric Exclusivity under 505A of the Federal Food, Drug and Cosmetic Act, U.S.F.D.A. (Revised, September 1999). During the instant pediatric exclusivity period, others were free to make, sell, offer to sell, import and use the compounds claimed in the ‘579 patent. Pediatric exclusivity is a regulatory privilege; a patent term extension is a patent privilege. Defendants are within their rights to advance the differences between the two. Indeed,

their argument that charging royalties for an expired patent is *per se* misuse because it extends the temporal scope of the patent is completely appropriate.

However, the Court notes that in *Princo* the Federal Circuit clarified that “[w]hile proof of an antitrust violation shows that the patentee has committed wrongful conduct having anticompetitive effects, that does not establish misuse of the patent in suit unless the conduct in question restricts the use of that patent and does so in one of the specific ways that have been held to be outside the otherwise broad scope of the patent grant.” *Princo* 616 F.3d at 1329. In other words, an antitrust violation may constitute misuse, but does not do so by definition. Therefore, because such a determination would likely depend on the particular facts involved and, even more likely, disputes regarding the governing law, it is inappropriate for the Court to resolve whether or not the alleged anticompetitive behavior constitutes patent misuse via a motion to strike. *Linker v. Custom-Bilt Machinery Inc.*, 594 F.Supp. 894, 898 (E.D.Pa.1984) (“A motion to strike an affirmative defense is not appropriate when the sufficiency of the defense depends on disputed issues of fact. Moreover, a motion to strike is not the appropriate procedure to determine disputed or unclear questions of law.”). Here, Defendants’ theory of the case is predicated on their contention that the relevant case law supports the conclusion the Plaintiff’s alleged conduct is patent misuse under *Brulotte*. Defendants should be allowed to test this theory and, as such, this Plaintiff’s challenge is more properly decided at the summary judgment stage.

Plaintiffs also allege that Defendants have not adequately alleged “patent leverage” as is required to advance a patent misuse defense. The Court notes that “patent leverage” may only need to be proven in cases not involving misuse *per se*, hence its *per se* characterization. Rather,

all that is required is that the patent be involved in the offending conduct. To the extent that leveraging need be shown in a *per se* case, as alleged here, merely pleading extension the temporal scope of the patent by charging post-expiration royalties would constitute “patent leverage” for the purpose of surviving a motion to strike. Furthermore, at this stage, Defendants need only plead patent leverage, not prove patent leverage.

As stated, motions to strike are inappropriate in cases where there are disputed issues of fact. In this case, the Court has determined that whether Plaintiffs’ conduct is misuse *per se* is more appropriately decided during summary judgment. At this point, factual issues remain as to whether Plaintiff’s conduct constitutes patent misuse *per se*, and furthermore, whether such misuse, if misuse it be, constitutes an antitrust violation and vice versa. Thus, it follows that the Court cannot properly strike Defendants’ misuse Defense until the Court rules on the relevant pleading requirements, which are contingent on a *per se* misuse characterization of Plaintiffs’ behavior. As regards Plaintiffs’ motion to strike, this is not a situation where Defendants’ misuse defense could not ultimately succeed, nor where the allegations have no possible relation to the controversy. Without such proof as a matter of law, the Court cannot, at this time, strike Defendants’ new patent misuse defense.

Accordingly, for the reasons set forth above and the Court finding that Defendants’ amendment is timely and not prejudicial to Plaintiffs,

IT IS on this 7th day of June, 2012,

ORDERED that Plaintiffs’ motion to strike Defendant’s new misuse defense is denied.

SO ORDERED.

s/ Jose L. Linares
JOSE L. LINARES
U.S. DISTRICT JUDGE